UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,096	09/26/2000	Linda S. Mansfield	MSU 4.1-526	7494

21036 7590 11/19/2008

IAN C. McLEOD, P.C.
2190 COMMONS PARKWAY
OKEMOS, MI 48864

EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
11/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LINDA S. MANSFIELD, MARY G. ROSSANO, ALICE J. MURPHY, and RUTH A. VRABLE

Appeal 2008-5433
Application 09/670,096
Technology Center 1600

Decided: November 19, 2008

Before ERIC GRIMES, LORA M. GREEN and RICHARD M. LEVOVITZ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 21 and 2.[1] We have jurisdiction under 35 U.S.C. § 6(b).

---

[1] This is the second time this application has been before us on appeal. *See* Appeal No. 2005-2386, decided May 25, 2006.

STATEMENT OF THE CASE

The claims are directed to a method of treating *Sarcocystis neurona*, and read as follows:

21. A method for treating an equid infected with *Sarcocystis neurona* comprising:

(a) providing a mixture of antibodies against a 16 ±4 kDa antigen and a 30 ±4 kDa antigen, both of which are specific to *Sarcocystis neurona*, wherein the antibodies are selected from the group consisting of polyclonal antibodies from serum from an animal immunized with the antigen and monoclonal antibodies from a hybridoma, and wherein the antibodies are in a pharmaceutically acceptable carrier; and

(b) inoculating the equid with the antibodies in the carrier to treat the equid.

2. The method composition [*sic*] of claim 21 wherein the antibodies are monoclonal antibodies.

The Examiner relies on the following references:

Ed Harlow et al. (Harlow), Antibodies - A Laboratory Manual 285-318 (1988).

Fang Ting Liang et al. (Liang 1997), "Micropreparative High Resolution Purification of Proteins by a Combination of Sodium Dodecyl Sulfate - Polyacrylamide Gel Electrophoresis, Isoelectric Focusing, and Membrane Blotting," 250 ANALYTICAL BIOCHEMISTRY 61-65 (1997).

Fang Ting Liang et al. (Liang 1998), "Evidence that Surface Proteins Sn14 and Sn16 of *Sarcocystic neurona* Merozoites Are Involved in Infection and Immunity," 66 INFECTION AND IMMUNITY 5, 1834-38 (1998).

We reverse.

ISSUE (Obviousness)

The Examiner concludes that claims 21 and 2 are obvious over the teachings of Liang 1998, Liang 1997, and Harlow.

Appellants contend that the combination would not render obvious a method of treating an equid infected with *Sarcocystis neurona* with the combination of an antibody to the 16kDa antigen and an antibody to the 30 kDa antigen. Thus, the issue on Appeal is: Whether the prior art renders obvious a method of treating an equid infected with *Sarcocystis neurona* with a mixture of an antibody to the 16kDa antigen and an antibody to the 30 kDa antigen?

FINDINGS OF FACT

FF1 The Examiner rejects claims 21 and 2 under 35 U.S.C. § 103(a) as being obvious over the combination of Liang 1998, Liang 1997, and Harlow (Ans. 2).

FF2 The Examiner relies on Liang 1998 for teaching "a method of inhibiting merozoite activity." (*Id.* at 3.)

FF3 The Examiner finds that Liang 1998 identified four major immunoblot bands from the serum and cerebrospinal fluid of horses with neurological symptoms typical of equine protozoal myeloencephalitis (EPM), corresponding to 30, 16, 14, and 11kDa proteins (*id.*). *Sarcocystis neurona* is the causative agent of EPM (Liang 1998, Abstract).

FF4 Specifically, Liang 1998 states that serum and CSF samples of horses with neurological symptoms typical of EPM were "tested for inhibitory activities on parasite infection by an in vitro neutralization assay." (Liang

1998, p. 1834, second column.) From those studies, Liang 1998 found that "Sn16 [the 16 kDa antigen] and Sn14 [the 14 kDa antigen] may have important roles during the initial stage of *S. neurona* infection and that antibody to Sn14 may be more effective in neutralization [of *Sarcocystis neurona*] than antibody to Sn16 [the 16 kDa antigen]. *No inhibitory activity correlating with antibody to Sn30 was noted*." (*Id.* at 1836, first column (emphasis added).)

FF5 Liang 1998 concludes that:

> Although monoclonal antibodies are often used to study parasitic proteins, the sera of naturally infected animals have unique advantages in that they can provide important information on protectively immunogenic proteins in the natural host. The parasite may express different proteins at different stages of in vivo or in vitro development; and some proteins may be expressed and function essentially only in vitro. Such proteins would be inappropriate targets for vaccine development. *S. neurona* infection of the horse induces production of antibodies to Sn16 and Sn14, indicating that these two proteins are expressed in vivo and are strong immunogens in the horse. Clearly, they warrant further investigation as candidate antigens for inclusion in vaccines against *S. neurona* infection.

(*Id.* at 1837, second column.)

FF6 Liang 1997 is drawn to the purification of *S. neurona* antigens (Liang 1997, p. 65, first column), and thus does not add to the teachings of Liang 1998.

FF7 Harlow is cited for teaching the generation of both polyclonal and monoclonal antibodies (Ans. 4).

FF8 The Examiner concludes:

> It would have been prima facie obvious to one, having ordinary skill the art at the time the invention was made to make either monoclonal or polyclonal antibodies to merozoite surface antigens including 16KD and 30KD because Liang [1998] taught antibodies to surface antigen can inhibit infection in neutralization assays. . . . Therefore, an artisan of ordinary skill would have been motivated to use readily available and purified surface antigens (Liang . . . 1997) from merozoites including 16KD and 30 KD as disclosed by the prior art Liang et al 1998 or Liang et al 1997 with a reasonable expectation of success for raising antibodies (monoclonal/polyclonal antibodies) by using well established immunization procedures . . . .

(Ans. 5.)

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that "the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

However, an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was,

independently, known in the prior art." *KSR*, 127 S. Ct. at 1741. "Often, it will be necessary . . . to look to interrelated teachings of multiple [references] . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed[.]" *Id.* at 1740-41. "[T]his analysis should be made explicit," *id.* at 1741, and it "can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.*

ANALYSIS

Appellants argue that Liang 1998 teaches that there is no inhibitory activity correlated with the antibody to the 30 kDa (Sn30) antigen, and thus there is no reason for the ordinary artisan to combine an antibody to the 16kDa antigen with antibody to the 30 kDa antigen for the treatment of an equid infected with *Sarcocystis neurona*, as required by the method of claim 21.

We agree. As noted by Appellants, Liang 1998 specifically teaches that "[n]o inhibitory activity correlating with antibody to Sn30 was noted" (FF4), and the Examiner has not pointed to any reason as to why the ordinary artisan, faced with that teaching, would have used a mixture of an antibody to the 16kDa antigen with antibody to the 30 kDa antigen for the treatment of an equid infected with *Sarcocystis neurona*. The rejection is therefore reversed.

CONCLUSIONS OF LAW

Thus, we conclude that the combination of references relied on by the Examiner would not have rendered obvious a method of treating an equid infected with *Sarcocystis neurona* with the mixture of an antibody to the 16kDa antigen and an antibody to the 30 kDa antigen.

REVERSED

clj

IAN C. McLEOD, P.C.
2190 COMMONS PARKWAY
OKEMOS, MI 48864